K033280
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BIOMET

510(k) Summary

Applicant/Sponsor: Biomet Orthopedics, Inc.

Contact Person: Patricia Sandborn Beres
Senior Regulatory Specialist

Proprietary Name: Discovery™ Elbow - Mosaic™ Distal Humeral Replacement System

Common Name: Elbow Prosthesis

Classification Name: Elbow joint metal/polymer constrained cemented prosthesis (888.3150)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

- Discovery™ Elbow (K013042)
- Modified Single Axle Total Elbow (K000683)
- 3-Piece Proximal Humeral Replacement System (K020045)
- Short and Long Soft Tissue Attachment Sleeves (K022079)

Device Description: The Discovery™ Elbow - Mosaic™ Distal Humeral Replacement System is an elbow replacement device designed for use in cases where there is distal humeral bone loss. The device consists of a ulnar stem with a pre-assembled bearing, a distal humeral component which, with a humeral condyle kit, completes the hinge of the elbow, an extramedullary modular distal segment for bone replacement and a intramedullary humeral stem. Soft tissue attachment sleeves, centering sleeves and canal cement plugs complete the system.

Indications for Use:

1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Revision where other devices or treatments have failed.
4. Correction of functional deformity.
5. Treatment of acute or chronic fractures with humeral epicondyle involvement, which are unmanageable using other treatment methods.
6. Oncology applications.

Summary of Technologies: The Discovery™ Elbow - Mosaic™ Distal Humeral Replacement System components (materials, design, sizes and indications), are similar or identical to the predicate devices.

Non-Clinical Testing/ Clinical Testing: None was provided as a basis of substantial equivalence.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 9 2003

Ms. Patricia Sandborn Beres
Senior Regulatory Specialist
Biomet Orthopedics Corp.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K033280
Trade/Device Name: Discovery Elbow – Mosaic Distal Humeral Replacement System
Regulation Number: 21 CFR 888.3150
Regulation Name: Elbow joint metal/polymer constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JDC
Dated: October 9, 2003
Received: October 10, 2003

Dear Ms. Beres:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Division Director
Division of General, Restorative,
And Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033280

Device Name: Discovery™ Elbow – Mosaic™ Distal Humeral Replacement System

Indications For Use:

The indications for use for the Discovery™ Elbow - Mosaic™ Distal Humeral Replacement System include:

1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis,
2. Rheumatoid arthritis
3. Revision procedures where other treatments or devices have failed
4. Correction of functional deformity
5. Treatment of acute and chronic fractures with humeral epicondyle involvement which are unmanageable using other treatment methods
6. Oncology applications

This device is intended to be used with bone cement.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Milleson

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...d Neurological ...

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